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- Admitted in TX only
- ** Admitted in CT only

October 15, 2004

 MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Re:

U.S. Patent Application No.: 09/852,966

For: USE OF CREATINE OR CREATINE COMPOUNDS FOR SKIN

PRESERVATION

Inventors: Kaddurah-Daouk, Rima

Filed: May 10, 2001

Our Ref. No.: AVZ-020CNRCE

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- Supplemental Information Disclosure Statement; 1.
- 2. PTO Form SB/08;
- 3. Australian Search Report;
- Copies of all publications cited in PTO Form SB/08 (4); and 4.
- 5. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

October 15, 2004

Date

Cynthia M. Soroos, Esq. Registration No. 53,623

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Cynthia M. Soroos, Esq. Registration No. 53,623 Attorney for Applicant



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To Initials Action Date

Australian Government
IP Australia

Discovery House, Phillip ACT 2606 PO Box 200, Woden ACT 2606 Australia Phone +612 6283 2999 Facsimile +612 6283 7999 www.ipaustralia.gov.au

10 February 2004

Your Ref: 34246AUP00

Examiner's first report on patent application no. 57616/00 by AVICENA GROUP, INC.

Last proposed amendment no. 2

Dear Ms Lewin,

I am replying to the request for examination. I have based this report on the pamphlet and the statement of proposed amendments under S104 of 23 January 2003. I have examined the application and I believe that there are lawful grounds of objection to the application. These grounds of objection are:

- 1. The claims in general are unclear because no clear limitation can be placed on the term "skin disorder." Given that creatine was well known for treating a wide variety of skin "ailments" before the priority date of the claim, it is unclear if the invention is supposed to reside in treating different disorders than the many it is known for.
- 2. The invention as generally claimed lacks novelty and an inventive step in the light of:
 - a) V US 4772591 A (MEISNER) 20 September 1988,*
 - b) US 5847003 A (PTCHELINTSEV et. al.) 8 December 1998,
 - c) WO 95/26182 A (BEIERSDORF AG) 5 October 1995,
 - d) US 5702688 A (YU et. al.) of 30 December 1997 (essentially similar disclosure to US 5883128 of 16 March 1999 and US 5886041 A of 23 March 1999, both cited against the corresponding US and EP application, and discussed in the IPER,
 - e) WO 97/42960 A (AVON PRODUCTS INC) 5 December 1997,
 - f) WO 97/12591 A (BEIERSDORD AG) published 10 April 1997,

^{*} Cited against the corresponding US and WO applications.

all of which disclose the use of creatine (individually or in conjunction with other active ingredients) for the treatment of a wide variety of skin disorders. By definition the compositions *per se* are also disclosed.

The following documents, all cited in the ISR, all disclose the use of creatine in compositions for treatment of cancers and related ailments. It would appear that a person skilled in the art would at least consider that such compositions would have potential in treating skin disorders such as skin cancers. Even if this is not the case, the compositions per se could be used for such methods:

- g) WO 92/08456 A (AMIRA INC) 29 May 1992,
- h) $\sqrt{\text{US }5321030 \text{ A (KADDURA-DAOUK et. al.) } 14 \text{ June } 1994,}$
- i)

 √ WO 94/16687 A (THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA)

 4 August 1999, and
- j) VUS 5676978 A (TEICHER et. al.) 14 October 1997.
- 3. There is no Notice of Entitlement on file. You will need to file one because an application without a Notice of Entitlement cannot be accepted.

I apologise for your application not being considered within the time set out in our Customer Service Charter. Currently the time between request and examination for all work in this technology is beyond that set out in the charter. We are refining our processes and reviewing our work distribution to address these delays.

You have 21 months from the date of this report to overcome all my objection(s) otherwise your application will lapse. You will need to pay a monthly fee for any response you file after 12 months from the date of this report.

Yours sincerely,

GRAEME J. BROXAM

Examiner of Patents, Section B2

Telephone: (02) 6283 2133



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kaddurah-Daouk, Rima

Serial No.: 09/852,966

Filed: May 10, 2001

For: USE OF CREATINE OR CREATINE COMPOUNDS FOR SKIN PRESERVATION

Attorney Docket No.: AVZ-020CNRCE

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Group Art Unit: 1614

Examiner: V.Y.Kim

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date set forth below.

October 15, 2004

Date of Signature and of Mail Deposit

By:

Cynth a M. Soroos, Esq.

Reg. No. 53,623

Attorney for Applicant

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicant and her Attorney have become aware of the following publications and information, cited in an Australian Search Report dated February 10, 2004 during the prosecution of 57616/00 which corresponds to the above referenced application. In accordance with 37 CFR §1.97, Applicant hereby submits these publications for the Examiner's consideration. These publications are cited on the enclosed PTO Form SB/08, and a copy of the Report and each publication cited thereon are enclosed as well.

Serial Number: 09/852,966 Page -2- Group Art Unit: 1614

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIYE & COCKFIELD, LLP

Cynthia M. Soroos, Esq. Registration No. 53,623 Attorney for Applicant

28 State Street Boston, MA 02109 (617) 227-7400

Date: October 15, 2004

EAH/CMS/MCA/les

Enclosures



PTO/SB/08a/b (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| Substitute for form 1449A/B/PTO | | | = | Complete if Known | | |
|---------------------------------|-----------------------------------|------|-----------|------------------------|----------------------|--|
| | | | | Application Number | 09/852,966 | |
| INFORMATION DISCLOSURE | | | | Filing Date | May 10, 2001 | |
| S | TATEMENT E | 3Y / | APPLICANT | First Named Inventor | Kaddurah-Daouk, Rima | |
| | | | | Art Unit | 1614 | |
| | (Use as many sheets as necessary) | | | Examiner Name | V.Y. Kim | |
| Sheet | 1 | of | 1 | Attorney Docket Number | AVZ-020CNRCE | |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | F1 | 5,702,688 | 12-30-1997 | Yu, et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|------|---|-----------------------------|--|---|--|
| Examiner Initials* | Cite | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | |
| | No.1 | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | F2 | WO 95/26182 A1 | 10-05-1995 | Beiersdorf AG | | |
| | F3 | WO 97/12591 A1 | 04-10-1997 | Beiersdorf AG | | |
| | F4 | WO 97/42960 A1 | 11-20-1997 | Avon Products Inc. | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | | |
|---------------------------------|--------------------------|---|----|--|--|--|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² | | | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Examiner | Date |
|-----------|------------|
| Signature | Considered |
| <u> </u> | |

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.